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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Peter Ghosh

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/560,790	Applicant(s) GHOSH, PETER	
	Examiner Karen Cochran Carlson	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29,30,32,35-64 and 66-69 is/are pending in the application.
- 4a) Of the above claim(s) 35-64 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20,30,32 and 67-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 4, 2009 has been entered.

Claims 1-28, 31, 33, 34, and 65 have been cancelled. Claims 29, 30, 32, 35-64, and 66-69 are currently pending. The Examiner has withdrawn Claims 35-64 and 66 from further consideration because these claims are drawn to non-elected inventions. Claims 20, 30, 32, and 67-69 are currently under examination.

Benefit of priority is to June 17, 2003.

Maintenance of Objections and Rejections:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below.

See the sequences set forth at 20+ , wherein no sequence identification numbers have been used to identify the sequences.

Applicants have not addressed this objection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 30, 32, and 67 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicants have not not provided a basis for SEQ ID NO: 8, and Applicants have not deleted SEQ ID NOs: 20-24 from disclosure. A new sequence listing is needed to delete these sequences.

Regarding SEQ ID NO: 8, the previous Office Action stated:

In Table 2,

RHLYPNGL**PEYSFLTTFR**,

RHLYPNGL**PEYSFLTTFM**,

RHLYPNGL**EEYSFLTTFR**, and

RHLYPNGL**EEYSFLTTFM** are taught. However, the entire sequence is not underlined, rather Y and NGL**PEYSFLTTFRTG** are underlined.

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The corresponding sequence in Table 3,

RNLYPSGLPEEYSFLTTFRM is taught. However, the entire sequence is not underlined and PEEYSFLTTFRMT is underlined.

Therefore, SEQ ID NO: 8 RHLYPNGLPEEYSFLTTFRM and SEQ ID NO: 23 RNLYPSGLPEEYSFLTTFRM are not taught in Table 2 or Table 3.

The Examiner has now demonstrated that at least 5 sequences (SEQ ID NO: 20-24) are not disclosed in the specification, based on Applicants assertion that the sequences are found in Tables 2 and 3 and the Examiner's own initiative to look elsewhere in the disclosure for the sequences. *The burden is now shifted back to Applicants to provide evidence that the sequences are not new matter. Applicants should specifically point out where in the disclosure that the sequences are taught in response to this Office Action.*

As noted in the previous Office Actions:

SEQ ID NO: 7 finds basis at page 20, line 21 of the specification, wherein the following sequence is presented:

(R)IGQDDLPGFDLISQFQIDK(A).

SEQ ID NO: 2 is finds basis at page 20, line 16 of the specification wherein the following sequence (K)SVSFSYK(G) is disclosed.

SEQ ID NO: 6 finds basis at page 20, line 20 wherein (K)HWSIWQIQDSSGK(E) is taught.

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SEQ ID NO: 9 is taught at page 21, line 23 as

(K)GLDGSLQTAAFSNLPSLFDSQWHK(I).

Basis for SEQ ID NO: 3, NO: 5, and NO: 11 is found at page 21, lines 12, 19, and 25, respectively.

Basis for newly added SEQ ID NO: 4 to Claim 29 is found at page 20, line 9.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29 and 30 and new claim 68 are again rejected under 35 U.S.C. 102(b) as being anticipated by Vaughan-Thomas et al. (2001; EMBL AF419343).

Vaughan-Thomas et al. teach the NC4 domain or fragment of bovine type IX collagen in articular cartilage having an amino acid length of 187. This sequence shares 70.5% identity with instant SEQ ID NO: 14 over the entire length of SEQ ID NO: 14 (245 amino acids), and is a fragment of having 91.4% identity over the 187 amino acids of the NC4 domain. The NC4 domain has a molecular weight of 20.9 kD. It appears that this peptide sequence is in hand because the citation does not state that the sequence

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is deduced from cDNA, for example. Therefore, the peptide was inherently placed into a composition. Additionally:

SEQ ID NO: 7 is found at amino acid residue 20 of Vaughan-Thomas et al.,

SEQ ID NO: 4 is found at amino acid residue 64.

SEQ ID NO: 8 is found at amino acid residue 72;

SEQ ID NO: 6 is found at amino acid residue 98;

SEQ ID NO: 2 is found at amino acid residue 123;

SEQ ID NO: 9 is found at amino acid residue 130;

SEQ ID NO: 3 is found at amino acid residue 154;

SEQ ID NO: 11 is found at amino acid residue 161; and

SEQ ID NO: 5 is found at amino acid residue 172.

Therefore, Vaughan-Thomas et al. teach a composition comprising a polypeptide fragment having at least 65% amino acid identity to SEQ ID NO: 14, having an amino acid sequence less than 250 amino acids, and comprising SEQ ID NO: 2, 3, 4, 5, 6, 7, 8, 9, and 11 (**Claim 29**), wherein the fragment has an amino acid of less than 30 kD or between 10 and 30 kD (**Claim 30, 68**).

Applicants arguments begin at page 12 of their response. Applicants urge that a person skilled in the art would know from reading the publication that the sequence deposited was a nucleic acid sequence and that the amino acid sequence is predicted and therefore the encoded polypeptide was not substantially purified. The amino acid sequence may have been deduced from the cDNA; however, Vaughn-Thomas et al.

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had the peptide in hand because 1) the title of the entry is drawn to the polypeptide: "The NC4 domain of bovine type IX collagen in articular cartilage" and 2) Vaughn-Thomas et al. have assigned an activity to this domain as being cell adhesion. Therefore, the polypeptide taught in Vaughn-Thomas et al. was in hand.

Applicants again argue that Vaughn-Thomas et al. do not disclose a composition useful for treating arthritis or induce tolerance to cartilage. These are intended uses; Vaughn-Thomas et al. teach a composition comprising the peptide claimed and therefore the claims are anticipated. Applicants may wish to amend their claims to distinguish over the polypeptide taught in Vaughn-Thomas et al. because Vaughn-Thomas et al. teach the structure claimed, and therefore that structure must have the same function as that claimed. In this situation, it appears that Applicants only further characterize a known polypeptide by additionally determining that the known polypeptide is also useful for treating arthritis and inducing tolerance to cartilage.

New Rejections:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29, 30, 32, and 67-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the independent claims, the term "substantially" is vague and indefinite.

No Claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656